

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE TABLE OF CONTENTS		PAGE iv
	TRANSMITTAL LETTER FPA-29		DATE 10/03/97

4. PROGRAM REGULATIONS

421.401: Introduction	4-1
421.402: Definitions	4-1
421.403: Eligible Members	4-2
421.404: Provider Eligibility	4-2
421.405: Staffing	4-2
(103 CMR 421.406 through 421.410 Reserved)	
421.411: Certification	4-4
421.412: Medical and Laboratory Services	4-4
421.413: Counseling	4-5
421.414: Follow-Up and Referral	4-5
421.415: Community Education	4-6
421.416: Outreach	4-6
421.417: Nonreimbursable Services	4-7
(130 CMR 421.418 through 421.420 Reserved)	
421.421: Coordination of Services	4-8
421.422: Emergency Backup	4-8
421.423: Recordkeeping Requirements	4-8
421.424: Quality Assurance	4-9
(130 CMR 421.425 Reserved)	
421.426: Consumer Participation	4-10
421.427: Assurance of Member Rights	4-10
(130 CMR 421.428 through 421.430 Reserved)	
421.431: Maximum Allowable Fees	4-11
421.432: Payment: Visits	4-11
421.433: Payment: Laboratory Services	4-12
421.434: Payment: Contraceptive Supplies and Drugs	4-12
(130 CMR 421.435 and 421.436 Reserved)	
421.437: The Norplant System of Contraception	4-14
421.438: Sterilization Services: Introduction	4-15
421.439: Sterilization Services: Informed Consent	4-16
421.440: Sterilization Services: Consent Form Requirements	4-17

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-1
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.401: Introduction

All providers of family planning agency services participating in MassHealth must comply with the regulations of the Division governing MassHealth, including, but not limited to, Division regulations set forth in 130 CMR 421.000 and in 130 CMR 450.000.

421.402: Definitions

The following terms used in 130 CMR 421.000 shall have the meanings given in 130 CMR 421.402 unless the context clearly requires a different meaning:

Annual Visit — a yearly visit during which comprehensive services, including medical, laboratory, and counseling services must be provided.

Initial Visit — a member's first visit during which comprehensive services, including medical, laboratory, and counseling services must be provided.

Institutionalized Individual — an individual who is:

- (1) involuntarily confined or detained, under a civil or criminal statute in a correctional or rehabilitative facility, including a psychiatric hospital or other facility for the care and treatment of mental illness; or
- (2) confined, under a voluntary commitment, in a psychiatric hospital or other facility for the care and treatment of mental illness.

Mentally Incompetent Individual — an individual who has been declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes that include the ability to consent to sterilization.

Routine Visit — a return visit, follow-up visit, or other visit that is neither an annual nor an initial visit.

Sterilization — any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing. A sterilization is "nontherapeutic" when the individual has chosen sterilization as a permanent method of contraception. A sterilization is "therapeutic" when it occurs as a necessary part of the treatment of an existing illness or injury or is medically indicated and performed in conjunction with surgery upon the genito-urinary tract.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-2
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.403: Eligible Members

- (A) (1) MassHealth Members. The Division covers family planning agency services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the Division's regulations. The Division's regulations at 130 CMR 450.105 specifically state, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
- (2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.
- (B) For information verifying member eligibility and coverage types, see 130 CMR 450.107.

421.404: Provider Eligibility

Payment for the services described in 130 CMR 421.000 will be made only to family planning agencies that are participating in MassHealth as of the date of service. The eligibility requirements for family planning agencies are as follows.

- (A) In State.
- (1) A family planning agency located in Massachusetts is eligible to participate in MassHealth only if it is certified by the Division as a family planning agency, in accordance with the requirements specified in 130 CMR 421.404 through 421.427.
- (2) The family planning agency must fulfill one of the following licensing requirements.
- (a) Family planning services must be provided in a facility licensed as a clinic or hospital by the Massachusetts Department of Public Health.
- (b) Family planning services must be provided under the license of a physician licensed by the Massachusetts Board of Registration in Medicine.
- (3) A family planning agency may provide family planning services in one or more service delivery sites, which must be located in freestanding clinics, community health centers, hospital outpatient departments, or hospital-licensed health centers.
- (B) Out of State. A family planning agency located outside of Massachusetts is eligible to participate in MassHealth only if it meets the licensing requirements in its state, participates in that state's medical assistance program (or equivalent), and meets the requirements specified in 130 CMR 421.404 through 421.427.

421.405: Staffing

- (A) Personnel Policies.
- (1) Current job descriptions must be available for all positions on the staff.
- (2) Written personnel policies must be available to all personnel.
- (3) An evaluation and review of the job performance of all personnel must be conducted annually.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-3
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

(B) Personnel Qualifications and Responsibilities.

(1) Administrator. A family planning agency must employ a full-time administrator who is responsible for supervising family planning services and for managing the family planning agency. The administrator must have demonstrated experience in the area of health-care administration.

(2) Medical Director. A family planning agency must employ a medical director who is a physician licensed by the Massachusetts Board of Registration in Medicine and who has demonstrated familiarity with gynecological examination and contraceptive prescription. The medical director is responsible for coordinating medical-staff activities as well as the medical aspects of the family planning program. The medical director assumes responsibility for the implementation of family planning protocol (see 130 CMR 421.412(E)); the maintenance of clinic standards; and the credentials review, training, and supervision of all staff physicians, nurse practitioners, and other medical personnel.

(3) Physician. A physician who is licensed by the Massachusetts Board of Registration in Medicine and who has demonstrated familiarity with gynecological examination and contraceptive prescription may provide medical care and medical supervision in a family planning agency. A physician must be either on site or on call during all clinic sessions.

(4) Nurse Practitioner. A nurse practitioner who is licensed by the Massachusetts Board of Registration in Nursing may work in a family planning agency in collaboration with a physician. A nurse practitioner must comply with all conditions of licensure and certification including all statutory and regulatory provisions governing nurse practitioner practice. On the basis of the nurse practitioner's education, experience, and clinical skills, the medical director must define and must reevaluate annually the nurse practitioner's responsibilities.

(5) Physician Assistant. A physician assistant who is a graduate of a program approved by the Massachusetts Board of Approval and Certification of Physician Assistant Programs may work in a family planning agency under the supervision of a physician. A physician assistant must comply with all statutory and regulatory provisions governing physician-assistant practice. On the basis of the physician assistant's education, experience, and clinical skills, the supervising physician must define and must reevaluate annually the physician assistant's responsibilities.

(6) Nurse. A nurse who is licensed by the Massachusetts Board of Registration in Nursing as a registered nurse or a licensed practical nurse may assist the physician, take medical histories, and conduct patient education and instruction about contraception in a family planning agency.

(7) Counselor or Outreach Worker. A counselor or outreach worker who has studied human anatomy and physiology, human reproduction, contraceptive methods, and counseling techniques may provide patient education, counseling, follow-up, and community education for a family planning agency.

(C) Inservice Training. Family planning agency personnel must participate in continuing education programs related to their activities, including orientation, on-the-job training, and regular inservice training.

(130 CMR 421.406 through 421.410 Reserved)

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-4
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.411: Certification

The Division will certify only a comprehensive family planning agency, defined as a public or private agency that demonstrates the capability of providing family planning medical services, family planning counseling services, follow-up health care, outreach, and community education.

421.412: Medical and Laboratory Services

(A) For an initial or annual visit, a family planning agency must provide all of the following medical and laboratory services:

- (1) a complete medical history (including family and interval);
- (2) a physical examination:
 - (a) for a member who is female, this includes thyroid, breast, heart, abdominal, speculum, pelvic, and rectal examinations, and measurements of height, weight, and blood pressure;
 - (b) for a member who is male, this includes thyroid, heart, genital, abdominal, and rectal examinations, and measurements of height, weight, and blood pressure;
- (3) a Pap smear (for a female member);
- (4) any laboratory test indicated by the member's history or examination (such a test may be provided directly or by referral);
- (5) a medically approved method of contraception, if appropriate; and
- (6) referrals for the screening, diagnosis, prevention, or treatment of general as well as reproductive medical conditions.

(B) For a routine visit, a family planning agency must provide medical and laboratory services necessary to monitor the member's contraceptive care or to follow-up on conditions requiring medical attention by agency personnel. These services must include, but are not limited to, the following:

- (1) update of medical history;
- (2) a physical examination that includes pelvic or genital examination;
- (3) measurements of blood pressure and weight;
- (4) any laboratory test indicated by the member's history or examination (such a test may be provided directly or by referral);
- (5) identification of any symptoms, conditions, or side effects that may contraindicate the method of contraception used;
- (6) assessment of the member's use of the method of contraception; and
- (7) referrals for the screening, diagnosis, prevention, or treatment of general as well as reproductive medical conditions.

(C) A family planning agency must make available all methods of contraception listed in Subchapter 6 of the Family Planning Agency Manual.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-5
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

(D) Physical examinations must be performed by a physician, a nurse practitioner, or a physician assistant. A physician must examine all members with medical problems and members who request to be seen by a physician. A nurse practitioner or physician assistant may examine members during an initial, annual, or routine visit. A physician must be on site or on call during all hours of operation.

(E) The family planning agency must have written medical protocols that include a periodicity schedule for return visits, procedures for follow-up for each method of contraception, procedures for care of high-risk patients, and emergency drug protocols.

421.413: Counseling

A family planning agency must provide counseling to assist members in achieving their family planning goals. Such counseling may include discussing general health, human anatomy, physiology, reproduction, and all available methods of contraception. Specific information about the safety of a method (potential side effects or complications), its effectiveness, its acceptability to member and partner, and its correct usage must be given. Surgical procedures must be discussed if the member prefers a permanent method of contraception. Follow-up counseling may include reinforcement of contraceptive instructions and reproductive information, discussion of member concerns or problems, and additional education.

421.414: Follow-Up and Referral

(A) Follow-Up. The family planning agency must have a system of contacting members who are patients of that family planning agency to remind them of their annual visits.

(B) Referral.

(1) A family planning agency must have arrangements with medical, social-service, and other community-service agencies to which appropriate referrals may be made for member problems identified during a family planning visit. The family planning agency must make referrals for necessary services if those services are not available on site. These services include, but are not limited to, the following:

- (a) treatment of medical problems beyond the scope of the family planning agency;
- (b) follow-up on positive results of tests for venereal disease or on other laboratory tests;
- (c) pregnancy-related services;
- (d) genetic counseling;
- (e) sterilization services or information; and
- (f) social case work beyond the scope of the family planning agency.

(2) All referrals must include follow-up to ensure that the referral process is completed successfully. If the referral was for an abnormal laboratory test result or a reproductive health problem, follow-up must include arrangements for receiving written results of tests or a report of initiated treatment.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-6
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.415: Community Education

(A) A family planning agency must provide community education. The objectives of a community education program include, but are not limited to, the following:

- (1) promoting community awareness and support of family planning services;
- (2) providing information about family planning or reproduction to interested groups or individuals;
- (3) integrating family planning education into educational institutions and community organizations; and
- (4) being a resource for other professionals in family planning education.

(B) A community education program must attempt to address the objectives in 130 CMR 421.415(A) through methods that are appropriate to the needs of the community. Such methods must include at least two of the following:

- (1) educational programs for adolescents, parents, professionals, and other targeted groups;
- (2) consultations with community organizations, schools, or church groups;
- (3) workshops or conferences;
- (4) health fairs;
- (5) speaking engagements;
- (6) media activities (for example, television or radio talk shows and newspaper articles);
- (7) participation in curriculum development and implementation; or
- (8) development of educational materials.

421.416: Outreach

(A) A family planning agency must perform outreach activities. The objectives of an outreach program include, but are not limited to, the following:

- (1) to make known to an entire community the availability of family planning services;
- (2) to encourage use of the agency's services by certain populations, such as adolescents and persons eligible for MassHealth, that are not currently receiving services adequate to meet their needs; and
- (3) to build linkages and referrals with local agencies and professionals.

(B) An outreach program must attempt to address the objectives in 130 CMR 421.416(A) through methods that are appropriate to the needs of the community. Any of the methods for providing community education that are listed in 130 CMR 421.415(B) may also be used for outreach. In addition, outreach methods must include one or more of the following:

- (1) publications for distribution;
- (2) advertisements;
- (3) public-service announcements and media spots;
- (4) information disseminated to groups and individuals in the target populations and, to the extent possible, in the native language and in the locality of the populations;
- (5) contact and information exchange with local transitional assistance offices; and
- (6) establishment of referral agreements with local agencies and professionals.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-7
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.417: Nonreimbursable Services

The Division does not pay for the treatment of male or female infertility, including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment.

(130 CMR 421.418 through 421.420 Reserved)

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-8
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.421: Coordination of Services

When a family planning agency is located in a community health center, a hospital, or another primary-care setting, the agency must demonstrate that family planning services are coordinated with and integrated into other services delivered on site. Such coordination includes at a minimum:

- (A) either one central medical record for each member in which all medical and health-care services are recorded, or a mechanism for transferring relevant information to medical records to ensure continuity of care;
- (B) avoidance of duplication of medical examinations and laboratory tests; and
- (C) in-house referrals, as appropriate.

421.422: Emergency Backup

A family planning agency must have provisions for 24-hour emergency backup. Each member must be given the emergency telephone number in writing at the time of initiation of services. The telephone number must also be displayed prominently in the family planning agency.

421.423: Recordkeeping Requirements

- (A) Payment for any service listed in 130 CMR 421.000 is conditioned upon its full and complete documentation in the member's medical record. A family planning agency must maintain a record of all medical and contraceptive services furnished to a member for at least four years following the date of service. Every member visit or telephone call with the staff must be recorded. The documentation must include the reason for each visit or telephone call and any action taken.
- (B) The medical record must contain, but is not limited to, the following information:
 - (1) the member's name, address, telephone number, date of birth, and MassHealth identification number;
 - (2) the date of service;
 - (3) the name, title, and signature of the person performing the service or making the contact;
 - (4) the type of visit (for example, annual or routine);
 - (5) medical history and history update;
 - (6) pertinent findings on examination;
 - (7) laboratory tests and results;
 - (8) abnormal findings and follow-up treatment;
 - (9) drugs administered or prescribed, including strength, dosage, route, regimen, and number of refills;

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-9
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

- (10) drugs dispensed, including strength, dosage, route, regimen, and number of units;
- (11) the contraceptive method used and any special instructions;
- (12) a summary of counseling; and
- (13) plans for follow-up.

(C) Basic information collected during previous visits with the member (for example, identifying data or medical history) need not be repeated in the medical record for subsequent visits as long as the entire medical record reflects continuity of care.

421.424: Quality Assurance

(A) Medical.

(1) The medical director or his or her designee must perform an on-site review of all physicians, nurse practitioners, and physician assistants within the first three months of their employment and thereafter annually for physicians and semiannually for nurse practitioners and physician assistants. Written reports of these reviews must be included in the personnel file. The on-site review must include observation and assessment of the clinical skills of the practitioner in caring for a variety of patients.

(2) The medical director or his or her designee must review at least four times a year a sample of the agency's records for adequacy of documentation and appropriateness of treatment and follow-up.

(B) General. A family planning agency must have on-going evaluation processes and appropriate plans of action for all program activities (including counseling and outreach services), clinic management, and availability of services.

(130 CMR 421.425 Reserved)

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-10
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.426: Consumer Participation

A family planning agency must be responsive to its consumers' needs and desires. A family planning agency must have at least one consumer on its board or a consumer advisory group. Consumer representatives may not be employed by the agency while they are members of the board or group. Matters subject to review by the board or group must include, but are not limited to, policy development, service delivery, and program evaluation.

421.427: Assurance of Member Rights

(A) Services must be made available to all members who request services, without regard to race, color, national origin, religion, creed, age, sex, parity, marital status, or handicap.

(B) A member's use of family planning services must be completely voluntary. No provider may coerce members in any way to receive services or to employ any particular method of family planning. Neither the Division nor any provider, nor any agent or employee of a provider, may mislead any member into believing that a decision to accept or not to accept family planning services will adversely affect his or her entitlement to benefits or services.

(C) The design of the agency's facilities must ensure privacy, confidentiality, and regard for the dignity of the member during personal interviews, consultations, medical examinations, and treatment. All information disclosed to agency personnel by the member or found as a result of the member's examination, care, and treatment must be held in strict confidentiality.

(130 CMR 421.428 through 421.430 Reserved)

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-11
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.431: Maximum Allowable Fees

The Massachusetts Division of Health Care Finance and Policy determines the maximum allowable fees for family planning agency services. Payment is always subject to the conditions, exclusions, and limitations set forth in these regulations. The payment for a service will be the lower of the following:

(A) the amount specified in the applicable fee schedule of the Division of Health Care Finance and Policy; or

(B) the agency's usual and customary fee (if the agency uses a sliding fee scale, this is the highest level of the scale).

421.432: Payment: Visits

(A) The payment for a family planning visit includes payment for the administrative operation of the family planning agency and for all aspects of service delivery, excluding laboratory tests, supplies, and drugs. Other than payment for laboratory tests, supplies, and drugs, no additional fees will be paid by the Division.

(B) For each member encounter, the Division pays for only one of the following types of visits.

(1) Comprehensive Visit. The Division pays for a comprehensive visit only when the encounter is an initial, annual, or extended visit. An initial or annual visit must include all of the medical, laboratory, and counseling services required in 130 CMR 421.412(A) and 421.413. The Division pays for only one initial or annual visit per member per year. An encounter is considered to be an extended visit when it is not routine in nature because extensive medical attention is necessary. Such a visit must last approximately 30 minutes. For an extended visit, the need for such services and the time elapsed must be documented in the medical record by the physician.

(2) Routine Visit. The Division pays for a routine visit when the encounter is a return, follow-up, or other visit that is not comprehensive. A routine visit must include all of the medical, laboratory, and counseling services required in 130 CMR 421.412(B) and 421.413.

(3) Minimal Service Visit. The Division pays for a minimal service visit when the encounter is a return visit consisting of counseling services only, or of a brief medical encounter and counseling services. The purpose of a minimal service visit is to reinforce contraceptive instructions, to monitor the member's use of a contraceptive method, or to provide education and counseling.

(C) The Division does not pay for a visit with the sole purpose of replenishing a member's supply of contraceptives. In this case, only the cost of the contraceptive supplies is reimbursable.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-12
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

(D) The family planning agency may bill for either a visit or a treatment/procedure, but may not bill for both a visit and a treatment/procedure to the same member on the same date when the visit and the treatment/procedure are performed in the same location. Examples of treatment/procedures are a vasectomy, a colposcopy, and a colposcopy with a biopsy.

421.433: Payment: Laboratory Services

(A) Reimbursable Services. The Division pays family planning agencies for laboratory services listed in Subchapter 6 of the Family Planning Agency Manual that are performed either at the agency or at an outside laboratory as a result of specimen referral. For tests performed at an outside laboratory, the Division pays according to the laboratory's charge to the agency or the laboratory fee schedule amount, whichever amount is less.

(B) Nonreimbursable Services. The Division does not pay family planning agencies for routine specimen collection and preparation for the purpose of clinical laboratory analysis (for example, venipunctures; urine, fecal, and sputum samples; Pap smears; cultures; and swabbing and scraping for removal of tissue); laboratory tests associated with male or female infertility; or such calculations as red blood cell indices, A/G ratio, creatinine clearance, and those ratios calculated as part of a profile.

(C) Profile or Panel Tests.

(1) A profile or panel test is defined as any group of tests, whether performed manually, automatedly, or semiautomatedly, that is ordered for a specified member on a specified day and has at least one of the following characteristics.

(a) The group of tests is designated as a profile or panel by the family planning agency performing the tests.

(b) The group of tests is performed by the agency at a usual and customary fee that is lower than the sum of that agency's usual and customary fees for the individual tests in that group.

(2) In no event may a family planning agency bill or be paid separately for each of the tests included in a profile test when a profile test has either been performed by that agency or requested by an authorized person.

(D) Individual Consideration. Some services listed in Subchapter 6 of the Family Planning Agency Manual are designated "I.C.," an abbreviation for individual consideration. This means that a specific fee could not be established. The payment for an I.C. service is determined by the Division's professional advisors based on the name of the test entered on the claim form.

421.434: Payment: Contraceptive Supplies and Drugs

(A) Contraceptive Supplies. The Division pays for contraceptive supplies according to Subchapter 6 of the Family Planning Agency Manual. If the family planning agency purchases supplies at a price lower than that allowed in the fee schedule, the agency must bill the Division at that lower price.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-13
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

(B) Drugs. The Division pays for drugs at the actual acquisition cost not to exceed the average wholesale price listed in the current edition of or supplements to the Drug Topics Red Book. Claims for dispensing drugs must include the following information: the name of the drug; the strength; the dosage; and the number of units. Claims without this information will be denied. Payment for drugs is determined on an individual consideration (I.C.) basis by the Division, based on the information entered on the claim form.

(130 CMR 421.435 and 421.436 Reserved)

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-14
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.437: The Norplant System of Contraception

(A) Eligible Providers. The Division pays family planning agencies for the insertion, reinsertion, and removal of the Norplant System of Contraception (Norplant) when the services are provided by a salaried physician, nurse practitioner, nurse midwife, or physician assistant. In order for the family planning agency to claim payment for Norplant services, the clinician performing the procedure must be trained by either the manufacturer of Norplant or another clinician who has been trained by the manufacturer.

(B) Reimbursable Services.

(1) Insertion. Payment for the insertion of Norplant is an all-inclusive fee for all services associated with insertion, including counseling and careful patient selection prior to insertion, the Norplant device, the insertion procedure, and one follow-up visit.

(2) Reinsertion. Payment for the reinsertion of Norplant includes removal of the old device, a new device, the insertion procedure, and one follow-up visit.

(3) Removal. The removal of a Norplant device without reinsertion is reimbursed as a separate procedure.

(C) Patient Selection, Counseling Prior to Insertion, and Follow-Up.

(1) In order to prevent premature removal of Norplant, the Division requires careful patient selection and counseling prior to insertion. Counseling must be in accordance with the manufacturer's guidelines, and must include a detailed discussion of potential side effects, contraindications, benefits and risks, and other contraceptive options. Payment for a counseling visit prior to the day of insertion is included in the reimbursement for insertion of Norplant. If the member decides not to proceed with the implant after counseling, the provider must bill the counseling as an office visit.

(2) An office visit following insertion is also required as a condition of reimbursement. The visit must include an examination of the insertion site for complications, a review of potential side effects, and follow-up instructions. Payment for the follow-up visit is included in the reimbursement for insertion and reinsertion. If more than one follow-up visit is necessary, the provider must bill each as an office visit.

(3) The provider must make every effort possible to ensure that the member returns for the follow-up visit. This must include, but not be limited to, scheduling the follow-up appointment on the day of insertion, recording the day of the follow-up appointment in the member's chart, mailing a reminder notice to the member, and reminding the member by telephone during the week of the scheduled appointment. The provider must document in the medical record the efforts made to ensure that the member returns for the follow-up visit. In order to ensure payment for the procedure, the provider must also document if the member fails to return for the follow-up visit.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-15
	TRANSMITTAL LETTER FPA-29		DATE 10/03/97

(D) Service Limitations.

- (1) The Division pays for the insertion and reinsertion of Norplant for female members of childbearing age with menstrual histories. The Division pays for the removal of Norplant for female members of all ages.
- (2) The Division pays for the insertion or reinsertion of Norplant only once per member per five-year period.
- (3) If the member has a Norplant device implanted, no other form of contraception is reimbursable, with the exception of condoms. If the Norplant device is removed for any reason, however, the Division will pay for alternative types of contraception.

(E) Payment.

- (1) Reimbursement for the services related to Norplant includes both the professional and the technical components involved. Therefore, if a family planning agency bills the Division for services, the individual practitioner who actually performed the service may not bill separately for the same services.
- (2) The Division reimburses family planning agencies for Norplant services at the rate set by the Massachusetts Division of Health Care Finance and Policy for those services (114.3 CMR 12.00).

421.438: Sterilization Services: Introduction

(A) Reimbursable Services. The Division pays for a sterilization service provided to a member who is male only if all of the following conditions are met.

- (1) The member has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 421.439, and such consent is documented in the manner and form described in 130 CMR 421.440.
- (2) The member is at least 18 years old at the time consent is obtained.
- (3) The member is not a mentally incompetent or institutionalized individual.

(B) Assurance of Member Rights. No provider may use any form of coercion in the provision of sterilization services. No provider, or agent or employee of a provider, may mislead any member into believing that a decision to have or not to have a sterilization will adversely affect the member's entitlement to benefits or services for which the member would otherwise be eligible.

(C) Retroactive Eligibility. The Division does not pay for a sterilization performed during the period of a member's retroactive eligibility unless all conditions for payment listed in 130 CMR 421.438(B) are met.

(D) Location in Which Sterilizations May Be Performed. Male sterilization must be performed by a licensed physician at the family planning agency's site.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-16
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

421.439: Sterilization Services: Informed Consent

A member's consent for sterilization is considered informed and voluntary only if such consent was obtained in accordance with the requirements specified in 130 CMR 421.439(A) and (B).

(A) Informed Consent Requirements.

- (1) The person who obtains consent (a physician, nurse, or counselor, for example) must orally provide all of the following information and advice to the member requesting sterilization:
 - (a) advice that the member is free to withhold or withdraw consent for the sterilization procedure at any time prior to that procedure without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the member might be entitled;
 - (b) a description of available alternative methods of family planning and birth control;
 - (c) advice that the sterilization procedure is considered irreversible;
 - (d) a thorough explanation of the specific sterilization procedure to be performed;
 - (e) a full description of the discomforts and risks that may accompany or follow the procedure, including an explanation of the type and possible effects of any anesthetic to be used;
 - (f) a full description of the benefits or advantages that may be expected as a result of the sterilization; and
 - (g) advice that the sterilization will not be performed for at least 30 days from the date consent is given.
- (2) The person who obtains consent must also:
 - (a) offer to answer any questions the member may have concerning the sterilization procedure;
 - (b) give the member a copy of the consent form;
 - (c) make suitable arrangements to ensure that the information and advice required by 130 CMR 421.439(A)(1) are effectively communicated to any member who is blind, deaf, or otherwise handicapped;
 - (d) provide an interpreter if the member does not understand the language used on the consent form or the language used by the person obtaining consent; and
 - (e) allow the member to have a witness of the member's choice present when consent is obtained.

(B) When Informed Consent Must Be Obtained.

- (1) A member's consent for sterilization is considered informed and voluntary only if such consent was obtained at least 30 days, but not more than 180 days, before the date of the sterilization procedure.
- (2) A member's consent for sterilization is not considered informed or voluntary if such consent was obtained or given while the member requesting sterilization was under the influence of alcohol or other substances that affect the individual's state of awareness.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series FAMILY PLANNING AGENCY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 421.000)		PAGE 4-17
	TRANSMITTAL LETTER FPA-29	DATE 10/03/97	

(3) Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the member of all of the information and advice specified in 130 CMR 421.439(A)(1).

421.440: Sterilization Services: Consent Form Requirements

Informed consent for sterilization must be documented by the completion of the Division's Consent for Sterilization form in accordance with the following requirements. (Instructions for obtaining the Consent for Sterilization forms are located in Subchapter 5 of the Family Planning Agency Manual.)

(A) Required Consent Form.

- (1) One of the following Consent for Sterilization forms must be used:
 - (a) CS-18 — for members aged 18 through 20; or
 - (b) CS-21 — for members aged 21 and older.
- (2) Under no circumstances will the Division accept any other consent for sterilization form.

(B) Required Signatures. The member, the interpreter (if one was required), and the person who obtained the consent for sterilization must all sign and date the Consent for Sterilization form (CS-18 or CS-21) at the time of consent. After performing the sterilization procedure, the physician must sign and date the form.

(C) Required Submission and Distribution of the Consent Form. Providers must complete and distribute the Consent for Sterilization form (CS-18 or CS-21) as follows:

- (1) the original to the member at the time of consent;
- (2) a copy in the member's permanent medical record at the site where the sterilization is performed; and
- (3) a copy attached to each claim made to the Division for sterilization services

REGULATORY AUTHORITY

130 CMR 421.000: M.G.L. c. 118E, ss. 7 and 12.